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Dockets Mngt. Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

RE: Docket No. 98N-1265

May 11, 1999

Dear Sirs:

I am writing in reference to the FDA's Docket No. 98N-1265, to express my concern and disapproval of the FDA's MOU published Jan. 21, 1999. I urge you to amend this MOU, especially Section 503A which governs the practice of pharmacy compounding.

The MOU, as written, severely limits the practice and interstate distribution of compounded drugs. The MOU places further unnecessary restrictions on consumer choices and commonly accepted professional pharmacy compounding practices.

Compounded drugs are often alternative solutions for individuals who have difficulty with or toxic reactions to patented (noncompounded) drugs. Others simply need or prefer the more specialized treatment or natural ingredients that compounded drugs offer.

The MOU will limit the rights of pharmacists to suggest alternatives to patients. Pharmacists frequently inform patients and physicians of alternative drugs that may be better suited to treating a particular problem or symptom. In effect, the MOU places a gag order on pharmacists who specialize in compounded drugs.

This MOU would drastically affect me. After going to various doctors who could not help me with my menopausal symptoms, and who prescribed several patented drugs with severe side effects for me, I have found a doctor in Washington, D.C. who has prescribed both a compounded estrogen replacement hormone and a compounded progesterone cream from a pharmacy in Wisconsin. My symptoms are now gone and I am able to function normally with no side effects. My body is very sensitive and can only tolerate mild, natural remedies, not toxic drugs.

For my sake and that of the many others like me, please amend this MOU, Docket No. 98N-1265. The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a government agency, the FDA also has a responsibility to the people, like me. The MOU must be amended.

98N-1265

Sincerely,
Mary R. Wolfe
Mary R. Wolfe

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P.S. Another point that I forgot to include is that this MOU severely limits the interstate distribution of compounded prescriptions, with no concern for limiting the same distribution practices for noncompounded prescriptions. This further restricts consumer choices. Specialty pharmacies currently fill a unique niche in response to the increasing demand for custom-compounded drugs, such as those using natural ingredients as an alternative to patented synthetics. Equal treatment under the law is called for! As the pharmacy I deal with is in Wisconsin and I live in Maryland, I would not be able to get my prescriptions!

This is outrageous and must not be allowed to occur.

MRW



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The Humane Society of the United States



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